Remarks

Claims 1-34 are canceled and claims 35-70 have been added. The new claims are fully supported by the specification as described in detail below.

In the March 17, 2008, the Examiner objected on formal grounds to the language of claim 22. This objection is moot in light of the cancellation of claim 22, and the added claims have been drafted in a manner that obviates the rejection.

The Examiner refers to 37 CFR §§ 1.58(a) and 1.83(a) in support of a requirement to delete sequence data from the specification. Applicant previously noted that these sections were amended in 2004, long after the instant application was filed, and that the instant application was fully in compliance with the requirements of 37 CFR §§ 1.58(a) and 1.83(a) in force at the time of filing of the application. In response, the Examiner queries why the rules are not retroactive. Applicant respectfully notes that the relevant section of the CFR states that the effective date for the rules was October 21, 2004, long after the PTO accepted the instant application as complete and ready for examination. Nothing in the rule states or implies that it is intended to be retroactive. Indeed, an effective date for a rule would be superfluous if a rule was simply assumed to be retroactive. Withdrawal of the objection respectfully is requested.

In the Office Action claim 33 was rejected under 35 USC § 112, first paragraph, for lack of written description. Claims 18, 21-22, and 32-34 were rejected under 35 USC § 103(a) as obvious over Dower and Kipriyanov. Claims 18, 21-22 and 32-34 also were rejected for obviousness-type double patenting over copending application 11/680,259. The specific ground for rejection, and applicant's response thereto, are set forth in detail below.

Support for new claims

The new claims are supported by the specification as originally filed. Claim 35 is supported in the specification as filed, *inter alia*, on page 12, lines 7 to 8; on page 10, lines 9 to 17 and on page 26, lines 25 to page 27, line 2. The term "wherein no interaction domain for interaction with a second domain present in the (poly) peptide/protein has been recombinantly fused to said member of the protein coat" is supported verbatim at page 5, lines 20-24 of the specification. "The term "modified" has been deleted from the term "modified variant." Furthermore, the term "second" in the term "second cysteine residue" has also been deleted. Claim 36 is supported in the specification as filed, *inter alia*, on page 4, lines 6 to 12 and on page

8, last paragraph. Claim 37 is supported, e.g., as shown for claim 35 and on page 6, penultimate and last paragraphs and by Example 1. The term "truncated variant" has been amended to read "truncated portion". Claim 38 is supported, *inter alia*, as shown above for claim 36. Support for claims 39 and 40 can be found in the specification as filed, e.g., on page 10, last paragraph to page 11, first paragraph. Claims 41 and 42 find support, e.g., on page 12, third paragraph and claims 43 and 44 are, *inter alia*, supported by the subject matter disclosed on page 12, first paragraph. Support for claim 45 can be found, in addition to the support already cited for claim 35 above, for example on page 11, last paragraph. Claim 46 is supported, e.g., as shown for claim 36, above. For claims 47 and 48, support can be found for example on page 5, lines 13 to 24. Support for claims 49 to 51 is, *inter alia*, as shown for claim 43. Support for any one of claims 52 to 59 is as shown, *inter alia*, for claim 35 above, and for claims 59 through 65 as shown above, e.g., for claim 41. Claim 66 is supported as shown above for claim 36. Claim 67 is supported in the specification as filed, *inter alia* and implicitly, on page 11, last paragraph in combination with the disclosure content of page 10, last paragraph to page 11, first paragraph. Support for claim 66 can be found, e.g., on page 10, first paragraph and page 12, first paragraph. Finally, support for claims 69 and 70 can be found, *inter alia*, as already shown above for claim 43.

Rejection under 35 USC § 112, first paragraph.

Claim 33 stands rejected under 35 USC § 112, first paragraph, for lack of written description. Specifically, the Examiner asserts that the specification lacks support for fungal, plant, insect or mammalian host cells. The Examiner notes that page 12, third paragraph, of the specification, recites:

> In the context of the present invention the term "host cell" may be any of a number commonly used in the production of heterologous proteins, including but not limited to bacteria, such as Escherichia coli (Ge et al., 1995), or Bacillus subtilis (Wu et al., 1993), fungi, such as yeasts (Horwitz et al., 1988; Ridder et al., 1995) or filamentous fungus (Nyyssonen et al., 1993), plant cells (Hiatt & Ma, 1993; Whitelam et al., 1994), insect cells (Potter et al., 1993; Ward et al., 1995), or mammalian cells (Trill et al., 1995).

However, the Examiner asserts that "applicant does not have support for utilizing fungal, plant, insect, or mammalian host cells." Applicant respectfully does not understand the basis of

the rejection, since the rejected uses are clearly described in the specification. Accordingly, applicant requests clarification of the rejection.

Rejection under 35 USC § 103(a)

Claims 18, 21-22, and 32-34 are rejected under 35 USC § 103(a) as obvious over Dower and Kipriyanov. Specifically, the Examiner asserts that Dower teaches host cells comprising vectors where one vector encodes a phage coat protein fused to additional amino acids including a cysteine, and a second vector encoding a polypeptide containing a cysteine and a purification tag of unknown sequence, but does not teach the location of the cysteine. Kipriyanov is cited as teaching a tag of 5 histidines and a cysteine. The Examiner alleges that it would have been obvious to combine the references because one of ordinary skill in the art would have been motivated to replace Dower's purification tag of undefined sequence with Kipriyanov's tag to yield "predictable" results. The Examiner further alleges that the ability of cysteine residues to form disulfides within and between antibody chains was well known at the time of filing the instant application. Applicant respectfully traverses.

Dower merely teaches phage display of Fab fragments where an entire VH or VL chain is fused to a phage coat protein and the complementary immunoglobulin chain is expressed in a manner that permits formation of the Fab fragment. Kipriyanov merely describes a purification tag containing a cysteine that is used for chemical modification. Nothing in either reference, or in the combination of references, teaches or suggests the instantly claimed invention, where attachment of a modified coat protein and a polypeptide occurs by formation of a disulfide bond. In particular, the present specification states that attachment by formation of a disulfide bond "refers to a situation, wherein the disulfide bond is responsible for the attachment, and wherein no interaction domain for interaction with a second domain present in the (poly)peptide/protein has been recombinantly fused to said member of the protein coat." See page 5, third paragraph, of the specification. This situation clearly distinguishes over Dower, where Fab fragment formation is mediated by interaction of the CH and CL domains. To make this distinction still more explicit, applicant has amended the claims as appropriate to recite that "no interaction domain for interaction with a second domain present in the (poly) peptide/protein has been recombinantly fused to said member of the protein coat."

The Examiner's comments that the ability of cysteine residues to form disulfides within and between antibody chains was well known at the time of filing the instant application. This

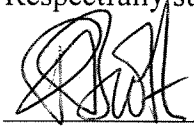
may be true, but it is not relevant to the patentability of the instant application. Antibody chains are stabilized by interaction of various constant and variable domains and are not attached merely by disulfide bonds, in contrast to the instantly claimed invention. Similarly, Kipriyanov does not teach or suggest vectors where expression leads to attachment of a variant protein and a polypeptide via a disulfide bond; rather, Kipriyanov is interested in using a cysteine as a nucleophile to chemically couple various moieties to the purification tag.

Conclusion

In view of the foregoing amendments and remarks, applicant respectfully submits that the claims are in condition for allowance. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,



Date: September 17, 2008

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